

**REMARKS**

Reconsideration and withdrawal of the rejections to Claims 78-99 pending in this application are requested for the reasons set forth herein.

By this amendment, the specification has been amended to update and correct the priority claim and an Abstract of the Disclosure has been added. Claim 78 has been amended to further define the invention. Claims 100-101 have been added to further define the invention. No new matter has been added.

**I. Priority**

By this Amendment, Applicants have amended the specification to delete the claim to priority to U.S. Application Nos. 08/954,355 and 08/437,348. As a result of the amendment, the present application claims priority only to parent application serial no. 08/988,137, filed December 23, 1997, now U.S. Patent No. 6,319,670.

**II. Abstract**

Applicants have added an "Abstract of the Disclosure" as requested by the Examiner.

**III. Written Description**

Claims 78-97 and 99 are rejected under 35 USC 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the Office Action, the Examiner argues:

All of these claims encompass cores and electrochemiluminescent compounds where the electrochemiluminescent moieties are "within said core". The dependent claims specifically identify a few particular core materials such as plastic, carbon, fullerenes and metals such as gold. The claims also encompass electrochemiluminescent moieties such as Ruthenium or Osmium, but the specification only exemplifies the use cores of colloidal gold, silica and titanium

oxide. There is no example in the specification in which an ECL reagent is “within said core”... In the application at the time of filing, there is no record or description, which would demonstrate conception of any microparticle, which has an ECL reagent “within said core”. That is, there is no description other than in the claim, which permits an ordinary practitioner to determine what species would function, how they would function or how such a core containing ECL reagents would be synthesized. Therefore, the claims fail to meet the written description requirement by encompassing species, which are not described in the specification.

[Office Action, page 4].

Applicants respectfully submit that the presently claimed subject matter is fully supported by the specification as originally filed in compliance with the first paragraph of 35 USC 112.

The Examiner’s attention is directed to MPEP §§ 2163 - 2163.07. The proper standard for determining whether an applicant has satisfied the “written description” requirement of the first paragraph of 35 USC § 112 is whether the applicant has conveyed with reasonable clarity to those skilled in the art that, as of the filing date of the application, the applicant was in possession of the invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971) [MPEP 2163.04]. The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97. [MPEP 2163.04].

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). [MPEP 2163].

Applicants submit the original specification adequately describes the claimed invention pursuant to the first paragraph of 35 USC 112. For example, page 20 of the original specification, clearly recites:

The electrochemiluminescent moiety can be immobilized on the particle in several ways. The electrochemiluminescent moieties may be directly attached to the immobilized assay-ligand, i.e., the binding reagent...**The ECL moiety may also be incorporated in the particle, e.g., by blending it in a plastic particle, by attaching it within the pores of a porous particle, or by enclosing it in a liposome.**

[Specification, page 20, emphasis added].

Thus, the specification clearly describes embodiments relating to a microparticle having a core and an ECL label incorporated within the core. Moreover, the specification describes different types of microparticles suitable for use of the invention (e.g., porous particles, blended plastic particles, and hollow particles such as liposomes), each of which are capable of incorporating ECL labels within their core. Applicants submit there is no basis provided in the Office Action for objecting to the claims under the “written description” requirement of 35 USC 112, first paragraph.

With respect to the Examiner’s statement “There is no example in the specification in which an ECL reagent is “within said core””, Applicants respectfully submit that the fact that the specification does not provide working examples of the claimed microparticles does not support the Examiner’s rejection since the absence of working examples is not relevant to determining whether claims comply with the written description requirement. With respect to the

“enablement requirement”, working examples are not required to satisfy the enablement requirement (MPEP Section 2164.02).

Thus, contrary to the Examiner’s suggestion, the specification need not provide examples or specific description of embodiments for the entire scope of the invention. Such details are unnecessary, as they are known in the art. Detailed procedures for making and using an invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention [MPEP §2164]. A patent does not teach, **and preferably omits**, what is well known in the art. *In re Buchner*, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984). [See also, MPEP § 2164.01].

However, to further the prosecution of the application, the claims have been amended to specify that the electrochemiluminescent moieties are metal-containing moieties.

Accordingly, Applicants respectfully urge that the rejection of claims 78-97 and 99 under 35 USC 112, first paragraph, is improper and should be withdrawn.

#### **IV. Definiteness**

Claims 78-97 and 99 are rejected under 35 USC 112, second paragraph, as allegedly being indefinite.

In the Office Action, the Examiner asserts that it “is vague and indefinite what is meant by the term ‘core’” (Office Action, page 5). Applicants respectfully submit that one of ordinary skill in the art would readily understand the meaning of the term “core” when properly construed in view of the specification. Terms in patent claims are not too vague unless they prevent one skilled in the art from understanding, in light of the specification, what is claimed. *Andrew*

*Corp. v. Gabriel Electronics, Inc.*, 6 USPQ2d 2010, 2013 (Fed. Cir. 1988); *U.S. v. Telectronics Inc.*, 8 USPQ2d 1217, 1220 (Fed. Cir. 1988); *Specialty Composites v. Cabot Corp.*, 6 USPQ2d 1601, 1604 (Fed. Cir. 1988). Thus, the term “core” is not to be read in a vacuum, but in view of the specification, including how the term is used in the claim. Claim 78 recites “A microparticle comprising a core and electrochemiluminescent moieties within said core...”. Thus, the term “core” refers to that of a microparticle. Applicants urge the claims are sufficiently clear and definite to one of ordinary skill in the art when properly construed in view of the specification. As stated in Sections 2173.01 and 2173.02 of the MPEP:

A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art. Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. [MPEP 2173.01]

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.

[MPEP 2173.01]

Applicants submit that one of ordinary skill in the art would under the metes and bounds of the term “core” as used in the claim.

In the Office Action, the Examiner also asserts:

It is vague and indefinite what is meant by the phrase “within said core”. It is unclear if this requires simple attachment of the ECL reagent to the core or if it actually requires formation of doped core which contains, for example, a mixture of Ruthenium and Gold. No such doped core is exemplified by the specification and consequently, the written description rejection is made based upon this interpretation.

[Office Action, page 5].

Applicants submit that the term “within said core” is sufficiently clear and definite pursuant to 35 USC 112, second paragraph. The specification clearly teaches:

**The ECL moiety may also be incorporated in the particle, e.g., by blending it in a plastic particle, by attaching it within the pores of a porous particle, or by enclosing it in a liposome.**

[Specification, page 20, emphasis added].

It is unclear why the Examiner is asserting that the claim needs to be further limited by defining how the labels are incorporated into the particle to comply with the second paragraph of 35 USC 112. As set forth in Section 2173.04 of the MPEP:

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. Undue breadth of the claim may be addressed under different statutory provisions, depending on the reasons for concluding that the claim is too broad. If the claim is too broad because it does not set forth that which applicants regard as their invention as evidenced by statements outside of the application as filed, a rejection under 35 U.S.C. 112, second paragraph would be appropriate. If the claim is too broad because it is not supported by the original description or by an enabling disclosure, a rejection under 35 U.S.C. 112, first paragraph would be appropriate. If the claim is too broad because it reads on the prior art, a rejection under either 35 U.S.C. 102 or 103 would be appropriate.

Applicants submit that the claims are sufficiently clear and definite to one of ordinary skill in the art pursuant to 35 USC § 112, second paragraph.

**V. The Inventive Subject Matter of the Present Claims are Not Unpatentable over the Cited References**

Claims 78, 85, 86, 87, 88, 94, 95, 96 and 97 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Blackburn et al., Clin. Chem., Vol. 37, No. 9 (1991), pp. 1534-1539 ("Blackburn"). Claims 78, 85, 86, 87, 88, 94, 95, 96, and 97 are rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 5,597,910 to Gudibande et al. ("Gudibande"). Claims 78-82, 84-97 and 99 are rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 5,679,519 to Oprandy et al. ("Oprandy"). Finally, claims 78-82, 85-91, 94-97 and 99 are rejected under 35 USC 103(a) as allegedly being obvious over PCT Patent Publication WO 90/05301 to Shah et al. ("Shah"). These rejections will be addressed collectively.

Applicants respectfully submit that the cited references do not anticipate the presently claimed subject matter. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). See, MPEP 2131.

Claim 78 recites "A microparticle comprising a core and electrochemiluminescent moieties within said core". Each of the cited references merely discloses

electrochemiluminescent labels. The fact such labels comprise Ru surrounded by bipyridyl groups does not support the Examiner's assertion that the labels anticipate the presently claimed subject matter. More specifically, the electrochemiluminescent labels are not microparticles having a core with electrochemiluminescent labels within the core. The "Ru" metal within the electrochemiluminescent label of the cited references, for example, is not itself an electrochemiluminescent label, but is instead a mere part of a label.

Accordingly, Applicants respectfully submit that each of the above cited rejections whether under 35 USC 102 or under 35 USC 103, are improper and should be withdrawn.

Claim 83 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,372,745 to Mandle et al. ("Mandle").

Applicants respectfully submit that *Mandle* does not disclose the presently claimed subject matter. In the Office Action, the Examiner asserts that *Mandle* teaches "that electrochemiluminescent particles are enclosed within a liposome", but then continue by describing *Mandle's* disclosure relating to fluorescer labels. Applicants submit that *Mandle* does not in any way relate to incorporating metal-containing electrochemiluminescent labels within microparticles. Instead, *Mandle* merely discloses a microencapsulated fluorescer material. Therefore, the rejection is improper and should be withdrawn.

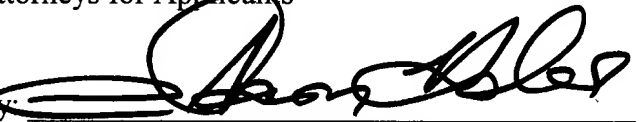


VI. Conclusion

In view of the amendments and remarks herein, withdrawal of the rejections to Claims 78-99 pending in this application is earnestly solicited, together with favorable reconsideration of the application and prompt issuance of a Notice of Allowance.

Respectfully submitted,

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**EXHIBIT A**

**MARKED-UP VERSION OF THE SPECIFICATION TO SHOW CHANGES**

This application is a continuation of U.S. Application Serial No. 08/988,137, filed December 23, 1997, [which is a continuation-in-part of U.S. Application Serial No. 08/954,355, filed October 20, 1997, which is a continuation of U.S. Application Serial No. 08/437,348, filed May 9, 1995 (now U.S. Patent No. 5,679,519), all of which are incorporated herein] now U.S. Patent No. 6,319,670, hereby incorporated by reference.

**EXHIBIT B**

**MARKED-UP VERSION OF CLAIMS TO SHOW CHANGES**

78. (Amended) A microparticle comprising a core and electrochemiluminescent moieties within said core, wherein said electrochemiluminescent moieties are metal-containing electrochemiluminescent moieties.

100. (New) A microparticle comprising metal-containing electrochemiluminescent moieties within said microparticle.

101. (New) The method of claim 98, wherein said assay-ligand immobilized on said surface and/or said assay-ligand immobilized on said electrode are capable of specifically binding with said analyte-of-interest.